

DISPOSABLE FEMININE HYGIENE PRODUCTS

The present specification is a continuation in part of USSN 10/371,491 filed February 21, 2003 and entitled disposable diaper for combating diaper rash.

The present invention relates to disposable feminine hygiene products for combating yeast infections. More particularly, the present invention relates to disposable feminine hygiene products selected from the group consisting of sanitary napkins, sanitary pads, panty shields and tampons for combating yeast infections, and a method for the manufacture thereof wherein said feminine hygiene products comprise a plurality of fibers coated with an antifungal Cu⁺⁺ cationic, water insoluble form of copper.

Paper products having various forms of copper incorporated therein have been described in the patent literature and thus e.g. in US Patent 1,947,451 published in February 1934 there is described a paper sheet having fungicidal and bacteriacidal properties carrying a predetermined amount of copper orthophenyl phenate precipitate.

Similarly many patents from decades ago such as US Patents 1,747,232; 1,846,185; 1,946,952; 1,988,231; 2,749,256; 3,492,464 and 3,713,963 disclose the incorporation of different forms of copper into paper however all of said patents as well as US Patent 1,947,451 teach the incorporation of soluble forms of copper for other purposes and do not teach or suggest the use of an antifungal Cu⁺⁺ cationic, water insoluble form of copper or the use thereof for preparing disposable feminine hygiene products.

Thus according to the present invention there is now provided a disposable feminine hygiene paper-based product selected from the group consisting of sanitary napkins, sanitary pads, panty shields and tampons for

combating yeast infections, said feminine hygiene paper product comprising a plurality of fibers coated with an antifungal Cu⁺⁺ cationic, water-insoluble form of copper.

In preferred embodiments of the present invention said fibers are cellulosic fibers.

In especially preferred embodiments of the present invention said coated fibers are disposed in said feminine hygiene paper product as randomly scattered fibers in a paper layer.

Preferably said coated fibers are dispersed in said feminine hygiene paper product in a layer positioned in said product in contact with the genital area of the user.

In another aspect of the present invention there is provided a method for the manufacture of a disposable feminine hygiene paper-based product for combating yeast infections comprising incorporating a plurality of fibers coated with an antifungal, Cu⁺⁺ cationic, water-insoluble form of copper in a layer of said disposable product adapted to be in contact with the genital area of the user.

In both WO 98/06508 and WO 98/06509 there are taught various aspects of a textile with a full or partial metal or metal oxide plating directly and securely bonded to the fibers thereof, wherein metal and metal oxides, including copper, are bonded to said fibers.

More specifically, in WO 98/06509 there is provided a process comprising the steps of: (a) providing a metallized textile, the metallized textile comprising: (i) a textile including fibers selected from the group consisting of natural fibers, synthetic cellulosic fibers, regenerated fibers, acrylic fibers,

polyolefin fibers, polyurethane fibers, vinyl fibers, and blends thereof, and (ii) a plating including materials selected from the group consisting of metals and metal oxides, the metallized textile characterized in that the plating is bonded directly to the fibers; and (b) incorporating the metallized textile in an article of manufacture.

In the context of said invention the term "textile" includes fibers, whether natural (for example, cotton, silk, wool, and linen) or synthetic yarns spun from those fibers, and woven, knit, and non-woven fabrics made of those yarns. The scope of said invention includes all natural fibers; and all synthetic fibers used in textile applications, including but not limited to synthetic cellulosic fibers (i.e., regenerated cellulose fibers such as rayon, and cellulose derivative fibers such as acetate fibers), regenerated protein fibers, acrylic fibers, polyolefin fibers, polyurethane fibers, and vinyl fibers, but excluding nylon and polyester fibers, and blends thereof.

Said invention comprised application to the products of an adaptation of technology used in the electrolyses plating of plastics, particularly printed circuit boards made of plastic, with metals. See, for example, Encyclopedia of Polymer Science and Engineering (Jacqueline I. Kroschwitz, editor), Wiley and Sons, 1987, vol. IX, pp 580-598. As applied to textiles, this process included two steps. The first step was the activation of the textile by precipitating catalytic noble metal nucleation sites on the textile. This was done by first soaking the textile in a solution of a low-oxidation-state reductant cation, and then soaking the textile in a solution of noble metal cations, preferably a solution of Pd^{++} cations, most preferably an acidic $PdCl_2$ solution. The low-oxidation-state cation reduces the noble metal cations to the noble metals themselves, while being oxidized to a higher oxidation state. Preferably, the reductant cation is one that is soluble in both the initial low oxidation state and the final high oxidation state, for example Sn^{++} , which is oxidized to Sn^{++++} , or Ti^{++} , which is oxidized to Ti^{++++} .

The second step was the reduction, in close proximity to the activated textile, of a metal cation whose reduction was catalyzed by a noble metal. The reducing agents used to reduce the cations typically were molecular species, for example, formaldehyde in the case of Cu⁺⁺. Because the reducing agents were oxidized, the metal cations are termed "oxidant cations" herein. The metallized textiles thus produced were characterized in that their metal plating was bonded directly to the textile fibers.

In WO 98/06508 there is described and claimed a composition of matter comprising:

(a) a textile including fibers selected from the group consisting of natural fibers, synthetic cellulosic fibers, regenerated protein fibers, acrylic fibers, polyolefin fibers, polyurethane fibers, vinyl fibers, and blends thereof; and
(b) a plating including materials selected from the group consisting of metals and metal oxides;
the composition of matter characterized in that said plating is bonded directly to said fibers.

Said publication also claims a composition of matter comprising:

(a) a textile including fibers selected from the group consisting of natural fibers, synthetic cellulosic fibers, regenerated protein fibers, acrylic fibers, polyolefin fibers, polyurethane fibers, vinyl fibers, and blends thereof; and
(b) a plurality of nucleation sites, each of said nucleation sites including at least one noble metal;
the composition of matter characterized by catalyzing the reduction of at least one metallic cationic species to a reduced metal, thereby plating said fibers with said reduced metal.

In addition, said publication teaches and claims processes for producing said products.

A preferred process for preparing a metallized textile according to said publication comprises the steps of:

- a) selecting a textile, in a form selected from the group consisting of yarn and fabric, said textile including fibers selected from the group consisting of natural fibers, synthetic cellulosic fibers, regenerated protein fibers, acrylic fibers, polyolefin fibers, polyurethane fibers, vinyl fibers, and blends thereof;
- b) soaking said textile in a solution containing at least one reductant cationic species having at least two positive oxidation states, said at least one cationic species being in a lower of said at least two positive oxidation states;
- c) soaking said textile in a solution containing at least one noble metal cationic species, thereby producing an activated textile; and
- d) reducing at least one oxidant cationic species in a medium in contact with said activated textile, thereby producing a metallized textile.

While the metallized fabrics produced according to said publications were described as being effective acaricides, it was found that they were also effective in preventing and/or treating bacterial, fungal and yeast infections which afflict various parts of the human body and that therefore the incorporation of at least a panel of a metallized textile material in an article of clothing could have extremely beneficial effect.

Thus, in US Patent 6,124,221 there is described and claimed an article of clothing having antibacterial, antifungal, and antiyeast properties, comprising at least a panel of a metallized textile, the textile including fibers selected from the group consisting of natural fibers, synthetic cellulosic fibers, regenerated protein fibers, acrylic fibers, polyolefin fibers, polyurethane fibers, vinyl fibers, and blends thereof, and having a plating including an antibacterial, antifungal and antiyeast effective amount of at least one oxidant cationic species of copper.

In said specification there was described that said article of clothing was effective against *Tinea Pedis*, against *Candida Albicans*, against *Thrush* and

against bacteria causing foot odor, selected from the group consisting of *brevibacterium*, *acinetobacter*, *micrococcus* and combinations thereof.

Thus, said invention was especially designed for preparation of articles such as underwear and articles of hosiery.

In WO 01/81671 there is described that textile fabrics incorporating fibers coated with a cationic form of copper are also effective for the inactivation of antibiotic resistant strains of bacteria and said cationic species of copper preferably comprises Cu^{++} ions.

It is to be noted however that textile chemistry is different than paper chemistry and it was not obvious to apply the teachings of said applications and patents which were directed to textile fabrics to paper chemistry to produce the disposable feminine hygiene paper-based products of the present invention.

More specifically it is to be noted that normal paper mulch is usually in an alkaline state with a pH which can vary from 8 to 11. While this atmosphere allows a reduction of copper to a cationic state to occur in an oxidation reduction process, the elements and the pH of the mulch will inhibit a full chemical reaction. The reduction process will upset the malleability of the mulch and the inhibition of the full reaction will in turn cause a limit to the antifungal quality of the mulch.

In order to have an effective level of antifungal activity and in order not to upset the proper production of paper, it was found according to the present invention that a fiber prepared with a plating of a cationic species of copper on it could be added to the mulch in the final stages of production without disturbing the production or antifungal qualities of the mulch. Since the copper on the fiber does not react to an alkaline solution or atmosphere, it was found that the full antifungal qualities were retained.

Thus, none of the above publications teach or suggest the subject matter of the present invention.

Furthermore as will be noted hereinafter in the production of paper acrylic glue is added to act as a binder for the paper and there was the possibility that the acrylic binder would encapsulate the copper compound and prevent the copper ions from being effective as an antifungal agent. Surprisingly this was found not to be the case and for this reason also the disposable feminine hygiene paper-based products of the present invention and their ability to combat yeast infections is unexpected and neither taught or suggested by the prior art.

While the invention will now be described in connection with certain preferred embodiments in the following examples and with reference to the attached figures, so that aspects thereof may be more fully understood and appreciated, it is not intended to limit the invention to these particular embodiments. On the contrary, it is intended to cover all alternatives, modifications and equivalents as may be included within the scope of the invention as defined by the appended claims. Thus, the following examples which include preferred embodiments will serve to illustrate the practice of this invention, it being understood that the particulars shown are by way of example and for purposes of illustrative discussion of preferred embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of formulation procedures as well as of the principles and conceptual aspects of the invention.

In the drawings:

FIG. 1 is a graphical representation of bacterial and fungal reduction with time using a sheet of paper comprising a plurality of fibers according to the present invention.

Example 1a) Preparation of the fibers

- i) Fibers were exposed to a tin dichloride solution and then rinsed in plain water.
- ii) Fibers were exposed to a palladium solution and then rinsed in plain water.
- iii) Fibers were exposed to a copper sulfate chelating solution.
- iv) Fibers were exposed to a reducing agent; and
- v) Fibers were allowed to dwell for no less than 2 minutes or until all fibers were plated by a dark brown form of copper.

b) Preparation of a paper incorporating said fibers

50 grams (dry weight) of a soft fibrous carton was prepared by chopping it into small pieces. The cut carton was placed in a soapy solution and heated to about 80°C and allowed to remain at that state for about 15 minutes to facilitate removal of any binders in the slurry.

The slurry was then rinsed with cold water and strained to remove excess liquid. The slurry was then placed in blender with a small amount of water and allowed to mix until a very fine slurry was obtained. The moist fine slurry was then divided into three small batches by weight each weighing about 90 grams after removal of excess liquid. The three batches were marked "A", "B", and "C". To sample A, 5 grams of finely chopped Cu coated cellulose fibers was added and allowed to mix in a blender. To sample B, 5 grams of Cuprous Oxide power was added and also allowed to mix in a blender. The Cuprous Oxide power particle size was 4 to 5 microns. Sample C was designated as a control to which no copper product was added. When a fine slurry of each was

obtained in its own blender, 5 grams of an acrylic glue was added to each to act as a binder for the paper.

A small amount of each slurry was placed between layers of absorbent paper and run through a squeeze roll at about 8 bars of pressure. This proved to be enough pressure to remove almost all the liquid in the slurry and still leave a flat paper. The paper was then dried using a hot air dryer.

Example 2

The produced paper samples were tested on Gram+ and Gram- bacteria, as well as on the common fungus, *Candida Albicans* (which is known to have resistance to copper) and which is known as a common cause of yeast infections in the genital area of women. The test methods used to measure efficacy were a west agar system and a diffusion system.

1 gram of each sample was placed in a sterile tube, containing 20 ml of peptone water. Each tube was inoculated with a suspension of the test microorganism. The control sample was prepared with 20 ml peptone water. The inoculated tubes were incubated at 30°C (*Candida Albicans*) or 35°C (Gram+, Gram-) for 2, 4, and 24 hours. The number of surviving bacteria and *Candida Albicans* micro-organisms was determined using the pour plate method.

Experimental Conditions:

Test Temperature	Room
Test Microorganisms	<i>E. coli</i> ATCC 8739, <i>Staphylococcus aureus</i> ATCC 6538, <i>Candida Albicans</i> ATCC 10231
Contact Time	0, 2, 4 and 24 hours
Counting Procedure	Pour Plate Count
Test Media	Tryptic Soy Agar, Difco
Temperature of Incubation	30°C, 35°C
Incubation Period	24-48 hours

Evaluation of Bactericidal and Fungicidal Activity of Cu⁺ Treated Matrix

Test Results:

Test Microorganism	CFU/ml			
	Escherichia coli ATCC 8739			
Exposure	0 hours	2 hours	4 hours	24 hours
Sample ID				
A (treated)	1.4x10 ⁴	3	0	N/A
B (treated)	1.3x10 ⁴	580	3	
C (untreated)	1.4x10 ⁴	6.6x10 ³	7.0x10 ³	
Peptone Water	1.5x10 ⁴	5.7x10 ³	790	

Test Microorganism	CFU/ml			
	Staphylococcus aureus ATCC 6538			
Exposure	0 hours	2 hours	4 hours	24 hours
Sample ID				
A (treated)	5.6x10 ³	5.8x10 ³	5.4x10 ³	0
B (treated)	5.2x10 ³	4.6x10 ³	4.7x10 ³	690
C (untreated)	5.3x10 ³	5.2x10 ³	8.0x10 ³	9.5x10 ³
Peptone Water	5.2x10 ³	7.2x10 ³	7.5x10 ³	8.8x10 ³

Test Microorganism	CFU/ml			
	Candida Albicans ATCC 10231			
Exposure	0 hours	2 hours	4 hours	24 hours
Sample ID				
A (treated)	2.0x10 ³	1.4x10 ³	1.1x10 ³	150
B (treated)	2.1x10 ³	1.7x10 ³	1.5x10 ³	850
C (untreated)	2.9x10 ³	1.5x10 ³	1.5x10 ³	1.1x10 ⁴
Peptone Water	2.8x10 ³	1.8x10 ³	1.7x10 ³	9.8x10 ⁴

Thus it will be noted that the treated paper samples of the present invention were extremely effective in reducing the concentration of Candida Albicans micro-organisms as well as significantly reducing the concentration of gram negative and gram positive bacteria.

It will be evident to those skilled in the art that the invention is not limited to the details of the foregoing illustrative examples and that the present invention may be embodied in other specific forms without departing from the essential attributes thereof, and it is therefore desired that the present

embodiments and examples be considered in all respects as illustrative and not restrictive, reference being made to the appended claims, rather than to the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.